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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,096	12/02/2003	David K. Swanson	03-0242 (US01)	6001

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EXAMINER	
ROANE, AARON F	

ART UNIT	PAPER NUMBER
3769	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/727,096	SWANSON, DAVID K.	
	Examiner	Art Unit	
	Aaron Roane	3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7,10,11,28,30-35,37-40,43,46,47 and 54-59* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7,10,11,28,30-35,37-40,43,46,47 and 54-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/24/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7, 10, 11, 28, 30, 40, 43, 46, 47 and 54-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samson (6,185,442) in view of Starver (4,469,105) in further view of Lundback (4,646,747).

Regarding claims 7, 11, 28, 30, 40 and 43, discloses a flexible tube (flexible tube into which wires 18 are disposed within and has a distal portion 17) defining a central axis and having a proximal end and a distal end; a suction device formed from a flexible material ("suction cup" 10 which is formed from a flexible material since it has a resilient wall 12), the suction device being connected to and coaxial with the distal end of the tube (portion 17) and having a flexible distal portion that includes a peripheral sealing surface (13) having a shape and a size for being removably securable to myocardial tissue, the suction device extending from the tube distal end such that the peripheral sealing surface is located distally of the tube distal end and extends outwardly beyond an outer surface of

the tube distal end such that suction device across the peripheral sealing surface is wider than the tube distal end; and a tissue electrode ("electrode" 16) that is too small to form a transmural lesion in myocardial tissue; wherein the suction device does not carry an apparatus that is capable of forming a transmural lesion in myocardial tissue, see col. 3:36-col.4:57 and figures 1-7, particularly figures 1 and 3. Samson fails to disclose the peripheral sealing surface of the suction device is flexible and the tissue stimulation element being supported on the peripheral sealing surface of the distal portion of the suction device. Samson also fails to disclose the tissue electrode is a tissue stimulation element/electrode and a source of stimulation energy operably connected to the stimulation element/electrode. Starver discloses a suction device having an electrode sensor (13) and teaches providing the suction device with alternate/equivalent embodiments where the electrode (13 in figure1 and 20 in figures 3-7) is placed on a flexible peripheral distal surface of the suction cup ("vacuum bell" 10) in order to provide an improved electrical connection and conduction between the tissue and the electrode, see col. 1:68-3:22 and col. 3:41-col. 6:25 and figures 1-7. Lundback discloses a surgical apparatus comprising an elongate flexible tube (8); a cup-shaped suction device (1-3 collectively) associated with the distal region of the tube, wherein the cup-shaped suction device is made from a flexible material (flexible bending portions of 2), a tissue electrode (the tissue contacting side of 30) on the suction device distal surface, see col. 3 and 4 and figures 1-4. Lundback teaches that the device is used as a diagnostic device or a therapeutic device, where the "diagnostic devices intended to be attached to the skin by means of the present vacuum-fixed holder are, for example, electrodes for

electroencephalography (ECG), electrodes for electromyography (EMG), sensors for skin temperature, humidity, and pH, biosensors and other sensors for indirect or direct measurement of blood gases, intramuscular sensor probes for, e.g., measurement of local peripheral circulation by laser-Doppler techniques, microphones for the registration of heart sounds, optical conductors for observation of the skin, etc. Therapeutic devices intended to be attached to the skin by means of the present vacuum-fixed holder are, e.g., electrodes for electrical stimulation of muscles, defibrillators, injectors for intramuscular administration of pharmaceuticals, electrodes for hyperthermal treatment, devices for percutaneous administration of pharmaceuticals, etc." Both Samson and Starver disclose electrodes that are used as sensors, while Lundback discloses electrodes used as sensors and/or used as tissue stimulation electrodes ("electrodes for electrical stimulation of muscles, defibrillators"). Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Samson, as taught by Starver, to provide the suction device with alternate/equivalent embodiments where the electrode is placed on a flexible peripheral distal surface of the suction cup in order to provide an improved electrical connection and conduction between the tissue and the electrode, and as further taught by Lundback, to provide the suction cup device with alternate use as a therapeutic device and using the electrode as a stimulation electrode, instead being used a diagnostic device using the electrode as a sensing electrode, and operably connecting the stimulation electrode to a source of stimulation energy.

Regarding claims 10 and 46, Samson discloses the suction device is substantially cup-shaped (10), see figures 1 and 3.

Regarding claim 47, Samson in view of Starver in further view of Lundback disclose the claimed invention, where Samson discloses at least one conducting wire (18) extending through the tube and connected to the tissue electrode, which is used as a tissue stimulation electrode as taught by Lundback.

Regarding claims 54-56, Samson in view of Starver in further view of Lundback disclose the claimed invention, see in particular the electrode (13 in figure 1 or 20 in figures 3-7) of Starver figures 1-7.

Regarding claims 57-59, Samson in view of Starver in further view of Lundback disclose the claimed invention, see in particular the sealing surface (13 in figure 1 or distal sealing surface of 10 in figures 3-7) of Starver figures 1-7.

Claims 31-33 and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samson (6,185,442) in view of Starver (4,469,105) in further view of Lundback (4,646,747) as applied to claims 7 and 28 above, and further in view of Ostroff et al. (7,149,575).

Regarding claims 31-33 and 37-39, Samson in view of Starver in further view of Lundback disclose the claimed invention except for the stimulation element defining a

perimeter of about 1.5 mm to 3 mm, a thickness of about 0.01 mm and a diameter of about 0.5 mm to 1.0 mm. The examiner takes official notice of the perimeter as it is trivial to provide the annular electrically conductive member 13 (electrode) of Starver with perimeter of about 1.5 mm to 3 mm corresponding to the cross-sectional area of 13 and a thickness of about 0.01 mm in order to electrode with its full functioning capabilities. It should be further noted that a circular perimeter of 1.5 mm to 3 mm yields a diameter of about 0.5 mm to 1 mm. As Applicant has traversed the official notice rejection, the examiner now provides a prior art reference which has been cited only to support the previous official notice rejection (see MPEP 2144.03(a-d), particularly 2144.03(d)). Specifically it is the cross-section of the electrode that is relevant for this rejection. Starver discloses an annular electrode (20) which is circular, see figure 7. Ostroff et al. (7,149,575) disclose an electrical tissue stimulating device and provide an electrode having a circular cross-section with diameter of 1-5 mm, see col. 5:351-67 and figure 1. Since the perimeter, **P**, of the electrode cross-section is given by

$$\mathbf{P} = 2 * \pi * \mathbf{r} = \pi * \mathbf{D},$$

where **D** is the diameter and **r** is the radius. Therefore, in order for the perimeter, **P**, to be about 1.5 mm to 3 mm, the diameter, **D**, must be about 0.47mm to 0.95mm. Since 1mm is about 0.95mm (a difference of less than 5.3%), the perimeter and diameter recitations have been met. Regarding the thickness of about 0.01mm, it can easily be seen from the **figure A** below, given a circular cross-section, a thickness can be defined which the circular cross-section inherently has and that is about 0.01mm. Figure A depicts the electrode's circular cross-section having a diameter, D and thickness, T. It should be

noted that thickness of 0.01mm is located almost at the top of the cross-section and for further illustration it should be noted the distance from the center of the circular cross-section to where the thickness is 0.01mm is equal to the square root of $(0.5mm)^2$ minus $(0.005mm)^2$.

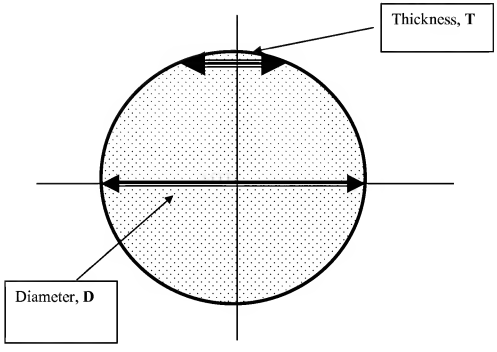

Figure A

Finally, Applicant may argue Starver doesn't disclose a circular cross-section. The examiner counters with the fact that a portion of the cross-section is circular (the upper portion) and it is that portion that defines (in view of the official notice and Ostroff et al. (7,149,575)) the recited dimensions.

Claims 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Samson (6,185,442) in view of Starver (4,469,105) in further view of Lundback (4,646,747)) as applied to claim 28 above, and further in view of Colliou et al. (US 7,020,531).

Regarding claims 34 and 35, Starver in view of Lundback disclose the claimed invention except for explicitly reciting that the source of stimulation is configured to provide stimulation pulses that are about 1 msec in duration, 10 mA and two stimulation pulses per second. Colliou et al. disclose a stimulating suction electrode device and teach providing the device with a power source capable of delivering 1 mA to 30 mA of current, a pulse width of 0.1 msec to 500 msec and a pulse burst repetition period of about 100 □sec to 20 msec in order to provide electrical stimulation, see col. 23, line 46 through col. 24, line 6 and figures 16A and 16B. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Starver in view of Lundback, as taught by Colliou et al., to provide the device with a power source capable of delivering 1 mA to 30 mA of current, a pulse width of 0.1 msec to 500 msec and a pulse burst repetition period of about 100 □sec to 20 msec in order to provide electrical stimulation to tissue.

Response to Arguments

Applicant's arguments with respect to claims 7, 10, 11, 28, 30-35, 37-40, 43, 46, 47 and 54-59 have been considered but are moot in view of the new ground(s) of rejection. The new grounds of rejection presented in this Office action is necessitated by Applicant's amendment.

In the hope of expediting prosecution of the present application, the examiner wishes to make some comments.

First, regarding the amendments to claims 7, 28 and 43 reciting the tissue stimulation element emits stimulation energy, Applicant has had an opportunity to review the prior art of record and consider various possible combinations thereof. Applicant should have been aware that Lundback disclosed the recited tissue stimulation electrode, its emission of stimulation energy as well as the stimulation power source. All three patents, Samson, Starver and Lundback disclose a suction cup and an electrodes used as sensors, while Lundback also discloses an alternative use for the electrode as a stimulation electrode. The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In re Keller, 642 F. 2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). In this regard, a conclusion of obviousness may be based on common knowledge and common sense of the person of ordinary skill in the art without any specific hint or suggestion in a particular reference. In re Bozek, 416 F .2d 1385, 1390, 163 USPQ 545, 549 (CCPA 1969).

Finally, regarding Applicant's traversal of the official notice rejection of claims 31-33 and 37-39 of the previous Office action (see section IV on pages 12-13 of the response filed 7/24/2008). The examiner has provided the necessary and sufficient support for the previous official notice rejection. That is, the examiner provided the rationale and prior art which render the claims obvious, see MPEP 2144.03(a-d), particularly 2144.03(d).

This action is made FINAL.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 8:30AM-7PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson can be reached on (571) 272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aaron Roane/
Examiner, Art Unit 3769

/Henry M. Johnson, III/
Supervisory Patent Examiner, Art Unit 3769